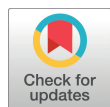


# Exhibit 11



## NEWS

# Johnson & Johnson recalls its Baby Powder after FDA finds asbestos in sample

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Johnson & Johnson, which for decades has insisted that its Baby Powder contains zero asbestos, has recalled one lot of the product—about 33 000 bottles—after the US Food and Drug Administration found asbestos in a sample bought online.

The company said that it was acting from “an abundance of caution” in withdrawing the lot numbered 22318RB, although the FDA advised consumers who had bought Baby Powder from that lot to “stop using it immediately.”

The FDA said that it had tested bottles from two different lots and found chrysotile asbestos—the type most associated with adverse health effects—in one of them. The agency has a long running programme of buying consumer products itself and testing them.<sup>1</sup>

Johnson & Johnson said in a statement that the FDA had found only “sub-trace levels of chrysotile asbestos contamination (no greater than 0.00002%).”<sup>2</sup> The company was unable to confirm whether the tested product was authentic or counterfeit or whether it had somehow been cross contaminated before or during testing.

## Knowledge of contamination

Johnson & Johnson “has a rigorous testing standard in place to ensure its cosmetic talc is safe and years of testing, including the FDA’s own testing on prior occasions—and as recently as last month—found no asbestos,” the company said.

But courts in New Jersey and Missouri have found that it knew of the presence of asbestos in its Baby Powder and sought to conceal this.<sup>3</sup> Investigations by Reuters and the *New York Times* published last December both cited internal company documents that seemed to show Johnson & Johnson executives and scientists fretting over asbestos contamination of mineral talc.<sup>4,5</sup>

In July *Bloomberg News* reported that a federal grand jury was probing whether executives had concealed any knowledge of asbestos contamination. Johnson & Johnson acknowledged having received a document subpoena from the Department of Justice on the matter.<sup>6</sup>

## Multiple legal battles

The news of a positive FDA test will come as a major boost to 15 500 US litigants who allege that Johnson & Johnson’s talcum products have caused ovarian cancer or mesothelioma. Early talcum cases went Johnson & Johnson’s way, but the tide of litigation has been turning against the company. In December a Missouri jury awarded \$4.7bn (£3.62bn; €4.21bn) to 22

women who said that Baby Powder had led to their ovarian cancer.

The company is also battling on multiple other legal fronts. In August a judge ordered the company to pay \$572m to the state of Oklahoma after finding that Johnson & Johnson had intentionally played down the dangers of opioids, and the company is also a defendant in a consolidated federal case over opioids, launched by thousands of cities and counties.

This month a Philadelphia jury ordered Johnson & Johnson to pay \$8bn to a man who had developed gynecomastia linked to risperidone. And last week the company paid \$117m to settle vaginal mesh claims from 41 states, although thousands of individual claims remain in the courts.

A study published this month in the *Journal of Occupational and Environmental Medicine* found asbestos in tissue samples from six of six patients tested who had mesothelioma.<sup>7</sup> All six had used talcum powder. The study authors are expert witnesses in talcum litigation.

Two former administrators of the Environmental Protection Agency wrote in the *New York Times* last week calling for the US to ban asbestos in line with 70 other countries including Australia, Canada, New Zealand, the UK, and almost all of Europe.<sup>8</sup>

- 1 US Food and Drug Administration. Baby powder manufacturer voluntarily recalls products for asbestos: FDA advises consumers to stop using affected products. 18 Oct 2019. <https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos>.
- 2 Johnson & Johnson. Johnson & Johnson Consumer Inc. to voluntarily recall a single lot of Johnson’s Baby Powder in the United States. 18 Oct 2019. <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>.
- 3 Dyer O. Johnson & Johnson knew for decades talcum powder contained asbestos, reports allege. *BMJ* 2018;363:k5430. 10.1136/bmj.k5430 30593486
- 4 Girion L. Special report: J&J knew for decades that asbestos lurked in its Baby Powder. Reuters. 14 Dec 2018. <https://www.reuters.com/article/us-johnson-johnson-cancer-special-report/special-report-jj-knew-for-decades-that-asbestos-lurked-in-its-powder-idUSKBN1OD1RQ>.
- 5 Rabin RC, Hsu T. Johnson & Johnson feared Baby Powder’s possible asbestos link for years. *New York Times* 2018 Dec 14. <https://www.nytimes.com/2018/12/14/business/baby-powder-asbestos-johnson-johnson.html>.
- 6 Feeley J. J&J denials of asbestos in baby powder spur criminal probe. *Bloomberg*. 12 Jul 2019. <https://www.bloomberg.com/news/articles/2019-07-12/jj-denials-of-asbestos-in-baby-powder-spur-u-s-criminal-probe>.
- 7 Moline J, Bevilacqua K, Alexandri M, Gordon RE. Mesothelioma associated with the use of cosmetic talc. *J Occup Environ Med* 2019; published online 10 Oct. 10.1097/JOM.0000000000001723.
- 8 McCarthy G, Reilly WK. Asbestos kills nearly 40,000 Americans a year. Ban it. *New York Times* 2019 Oct 15. <https://www.nytimes.com/2019/10/15/opinion/asbestos-epa-trump.html>.

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